FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
February 22, 2012

AGENDA

The committee will discuss the safety and efficacy of new drug application (NDA) 22–580, proposed trade name QNEXA (phentermine/topiramate) Controlled-Release Capsules, manufactured by VIVUS, Inc., as an adjunct to diet and exercise for weight management in patients with a body mass index (BMI) equal to or greater than 30 kilograms (kg) per square meter or a BMI equal to or greater than 27 kg per square meter if accompanied by weight-related co-morbidities.

8:00 a.m.	Call to Order and Introduction of Committee	**Abraham Thomas, M.D., M.P.H., FACP** Chair, EMDAC
8:05 a.m.	Conflict of Interest Statement	**Paul T. Tran, R.Ph** Designated Federal Officer, EMDAC
8:15 a.m.	Introduction/Background	**Eric C. Colman, M.D.** Deputy Director Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation (ODE) II Office of New Drugs (OND), CDER, FDA
8:30 a.m.	**SPONSOR PRESENTATION**	**Vivus, Inc.**
	Introduction	**Peter Tam** President Vivus, Inc.
	Review of Efficacy	**Wesley Day, Ph.D.** Vice President, Clinical Development Vivus, Inc.
	Review of Safety	**Neil Gesundheit, M.D., M.P.H.** Stanford University School of Medicine Stanford, California
	Review of Cardiovascular Safety	**Peter Kowey, M.D.** Lankenau Medical Center Wynnewood, Pennsylvania

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AGENDA (cont.)

	Review of Teratogenicity	**Gary Shaw, Ph.D.** Professor Division of Neonatal and Developmental Medicine Department of Pediatrics Stanford University School of Medicine Palo Alto, California
	Clinical Perspective On Teratogenicity	**Anthony Scialli, M.D.** Tetra Tech Sciences Arlington, Virginia
	Cardiovascular Perspective	**A. Michael Lincoff, M.D.** Cardiovascular Medicine Cleveland Clinic Cleveland, Ohio
	Medical Need and Risk Benefit	**Arya Sharma, M.D., Ph.D., D.Sc.** Obesity Research & Management University of Alberta Royal Alexandra Hospital Edmonton, Canada
9:45 a.m.	Clarifying Questions from the Committee	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATION**	
	Review of Phentermine/Topiramate (PHEN/TPM) Efficacy and Cardiovascular Safety	**Mary D. Roberts, M.D.** Clinical Reviewer DMEP, ODE II, OND, CDER, FDA
	SPEAKER PRESENTATION	
	Use of Monotherapy Topiramate in Pregnancy and Risk of Oral Clefts	**Suzanne M. Gilboa, Ph.D.** National Center on Birth Defects and Developmental Disabilities (CDC) Atlanta, Georgia

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	FDA PRESENTATION	
	Review of Studies on Topiramate Use in Pregnancy and Risk of Oral Clefts and Major Congenital Malformations	**Julia Ju, Pharm.D., Ph.D.** Pharmacoepidemiologist Division of Epidemiology I Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Risk Management Options for Phentermine/Topiramate	**Joyce Weaver, Pharm.D.** Senior Drug Risk Management Analyst Division of Risk Management Office of Medication Error Prevention and Risk Management (OMEPRM) OSE, CDER, FDA
11:45 a.m.	**SPONSOR PRESENTATION**	**Vivus, Inc.**
	Qnexa REMS	**Barbara Troupin, M.D.** Senior Director, Global Medical Affairs Vivus, Inc.
12:00 p.m.	Clarifying Questions from the Committee	
12:15 p.m.	**LUNCH**	
1:15 p.m.	Open Public Hearing Session	
2:15 p.m.	Questions to the Committee/Committee Discussion	
2:45 p.m.	**BREAK**	
3:00 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	